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16 UNITED STATES DISTRICT COURT
17 NORTHERN DISTRICT OF CALIFORNIA
18 (SAN JOSE DIVISION)

19 GILEAD SCIENCES, INC.,

20 Plaintiff and Counterdefendant,

21 v.

22 MERCK & CO, INC. (Defendant only), MERCK
23 SHARP & DOHME CORP. and ISIS
PHARMACEUTICALS, INC.,

24 Defendants and Counterclaimants.
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Case No. 5:13-cv-04057-BLF/PSG

**GILEAD'S [PROPOSED] INSTRUCTION
NO. 24 RE ENABLEMENT**

DISPUTED INSTRUCTION NO. 24 RE ENABLEMENT PROPOSED BY GILEAD

A patent claim is invalid if the patent at the time it was filed did not contain a description of the claimed invention that is sufficiently full and clear to enable a person of ordinary skill in the field at the time to make and use the full scope of the invention. This is known as the “enablement” requirement. The purpose of the enablement requirement is to ensure that the public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims. As such, the specification must teach those of skill in the art how to make and how to use the invention as broadly as it is claimed.

The patent is not required to disclose information that would be known to persons of skill in the art. The patent may be enabling even though it does not expressly state some information if a person of ordinary skill in the field ~~of the patent~~ could make and use the invention without having to do excessive experimentation. In determining whether excessive experimentation is required, you may consider the following factors:

- the scope of the claimed invention;
- the amount of guidance presented in the patent;
- the amount of experimentation necessary;
- the time and cost of any necessary experimentation;
- how routine any necessary experimentation is in the field;
- whether the patent discloses specific working examples of the claimed invention;
- the nature and predictability of the field; and
- the level of ordinary skill in the field.

~~The enablement requirement is met if the specification enables any mode of making and using the invention, provided that the full scope of the invention is enabled. The patent need not enable an optimized or commercially viable process or method of practicing the invention unless the claims specify that the invention is directed at an optimized or commercially viable process. Nor must the patent enable a person of skill in the art to obtain regulatory approval of the claimed invention, such as approval from the FDA to sell a pharmaceutical product.~~ For a patent to satisfy the enablement

1 requirement, the patent's disclosure need not show that the claimed invention is commercially
2 viable or eligible for FDA approval.

3 The "how to use" prong of the enablement requirement further requires that the specification
4 disclose a practical utility for the invention. In other words, the specification must disclose a
5 practical use for the invention.

6 The question of whether a patent is enabling is judged as of the date the application for the
7 patent was first filed, in this case January 18, 2002.

8 Gilead's position:

9 Gilead's additional proposed language to the first paragraph is taken from *National Recovery*
10 *Technologies, Inc. v. Magnetic Separation Systems, Inc.*, 166 F.3d 1190, 1195-96 (Fed. Cir. 1999).
11 Gilead proposes adding this language to explain the purpose of the enablement requirement, similar
to the language included in the first paragraph of the written description instruction that explains the
purpose of that requirement.

12 Rather than using Merck's proposed instruction that "[t]he patent need not enable an optimized or
13 commercially viable process or method of practicing the invention unless the claims specify that the
invention is directed at an optimized or commercially viable process. Nor must the patent enable a
14 person of skill in the art to obtain regulatory approval of the claimed invention, such as approval
from the FDA to sell a pharmaceutical product," Gilead proposes here more neutral and streamlined
15 language to address those concepts that does not use two sentences to overemphasize things that are
not required for enablement. For example, attached are two demonstrative excerpts disclosed by
16 Merck for use with their experts, where it is apparent that Merck intends to unduly emphasize both
of these points in their testimony.

17 Merck's proposed instruction that "[t]he enablement requirement is met if the specification enables
any mode of making and using the invention" is also inappropriate and unnecessary. If that
18 language appears in the instruction, Merck is likely to argue that enablement of a single
embodiment would be sufficient to enable the claim. While Gilead disputes that the specification
19 enables even that, Merck's argument on that issue would be incorrect as a matter of law. *See In re*
Vaeck, 947 F.2d 488, 495-96 (Fed. Cir. 1991) ("[T]here must be sufficient disclosure, either through
20 illustrative examples or terminology, to teach those of ordinary skill how to make and how to use
the invention as broadly as it is claimed. This means that the disclosure must adequately guide the
21 art worker to determine, without undue experimentation, which species among all those
encompassed by the claimed genus possess the disclosed utility."). Merck's language on "any
22 mode of making and using" comes from *Johns Hopkins University v. CellPro, Inc.*, 152 F.3d 1342
(Fed. Cir. 1998). In that case, the claims recited a genus of antibodies. The specification disclosed
23 one method for producing antibodies. That method could be used to produce many different
antibodies within the scope of the claims. That case is distinguishable from the situation here,
24 where Merck's specification fails to disclose a single example of a compound failing within the
scope of the claims or data for any compound within the scope of the claims.
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